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APR 1 5 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: January 27, 2010

1. Company and Correspondent making the submission:

Name – Shanghai 3F Electronics Co., Ltd.
Address – Building 3, No. 128, Jiujing Road,
Shanghai, China
Telephone – +86-21-67696500/51695200 ext: 8022
Fax – +86-21-67696296
Contact – Mr. Lu Yulin
Email – rmdlu@3fmedical.cn

2. Device :

Trade/proprietary name: PMS8210A (IRIS) Patient Monitor/ Multi-Parameter Patient Monitor

Common Name : Multi-parameter Patient Monitor

Classification of the device: Class II

Panels: Cardiovascular, General Hospital, Anesthesiology

Product code: 21CFR870.2700, Oximeter, DQA
21CFR870.2300, Monitor, Physiological, MWI
21CFR880.2910, Thermometer, Electronic, Clinical, FLL
21CFR871.1130, System, Measurement, Blood Pressure, DXN

Establishment Registration Number : None Yet

Predicate Devices:

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Predicate Model	Manufacturer	K Number	Submitted Device
PM-9000 EXPRESS PATIENT MONITOR	Shenzhen Mindtay Bio-medical Electronics Co., LTD	K053234	PMS8210A (Iris) Patient Monitor/ Multi-Parameter Patient Monitor

3. Description :

3.1 General

PMS8210A Patient Monitor is a battery or line-powered patient monitor. The Patient Monitor acquires the physiological signals such as ECG, respiration (RESP), Non-Invasive blood pressure (NIBP), Saturation of pulse oxygen (SPO2), Temperature (TEMP), Heart rate (HR) and Pulse Rate (PR).

The signals are converted into digital data and processed, examines the data for alarm conditions and displays the data. The monitor also provides operating control for the user.

The patient monitor is intended to be used in a hospital clinical area such as intensive care units, cardiac care units, operation room, emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the patient. The PMS8210A patient monitor is intended to be used only under regular supervision of clinical personnel. The intended location of use is clinics.

4. Indication for use :

The PMS8210A Patient Monitor is a multi-parameters monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PMS8210A Patient Monitor has certain features and functions.

The patient parameters that can be monitored by PMS8210A Patient Monitor are: ECG(3-lead or 5-lead selectable), Heart Rate(HR), Pulse Rate(PR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP),

Arterial Hemoglobin Oxygen Saturation(SpO2) and Temperature (TEMP). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PMS8210A Patient Monitor is intended for use in a health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PMS8210A Patient Monitor is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician.

5. Comparison with predicate device: - Please see next page for the comparison table.

Table of Comparison to Predicate Device

1. General Specifications (i.e. physical/electrical)

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
Physical dimension/weight	Dimensions: 250 (W)×180 (H)× 180 (D) (mm) Weight : 2.0kg	Dimensions: 318(W)×270(H)×137(D) (mm) Weight: <7.5kg
Display	7 segment LED + 3.2" colorful TFT LCD (320×240)	10.4" color TFT LCD(800×600)
Button	keys – front panel	Soft keys – front panel
Type, Degree of protection against electric shock	AC power adapter Electr. Class Ⅰ and internal power supply	AC power adapter Electr. Class Ⅰ and internal power supply
Power supply	100～240VAC(±10%), 50/60Hz(±3Hz),45VA	100～240VAC(± 10%), 50/60Hz(±3Hz),140VA
Internal power source	Insetting sealed lithium batter：2200mAh and 4400mAh	Sealed Lead acid battery(for 2 pieces) And insetting li-ion battery(for 2 pieces)
Battery charging indicator	Yes	Yes
Low battery indicator	Yes	Yes
Battery charge time, typ.	2200mAh : approx. 3 hours 4400mAh : approx. 6 hours	Acid battery: approx. 12 hours And li-ion battery: approx. 6.5 hours
Flammable anesthetics	not suitable	not suitable
Operating condition	Temperature: 0°C to 40°C (32°F to 104°F) Relative Humidity: ≤95%(non-condensing)	Temperature: 0°C to 40°C (32° F to 104° F) Relative Humidity: 15%~95% (non-condensing)
Storage condition	Temperature: - 40°C to 55°C (-40°F to 131°F) Relative Humidity: ≤95% (non-condensing)	Temperature: - 20°C to 60°C (-4°F to 140°F) Relative Humidity: 10% ~ 95%(non-condensing)
EMC	IEC 60601-1-2:2007	IEC 60601-1-2:2001+A1:2004
Power on self test	Yes	Yes
Optional printer	Yes	Yes

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2. ECG

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
Lead	3lead(RA,LA,LL); 5lead(RA,RL,LA,LL,V)).	3lead(RA,LA,LL); 5lead(RA,RL,LA,LL,V)); 10lead(RA,RL,LA,LL,V1-V6)).
Lead option	Monitor lead(3 lead) / standard lead(5 lead)	3 lead/ 5 lead/ 12 lead
Gain	×0.5; ×1.	×0.125; ×0.25; ×0.5; ×1; ×2;auto.
Sweep speed	12.5mm/s, 25mm/s, 50mm/s	12.5mm/s, 25mm/s, 50mm/s
Range of heart rate monitoring	Adult: 20~300 bpm; Neonate/ Pediatric: 20~350 bpm	Adult: 15~300 bpm; Neonate/ Pediatric: 15~350 bpm
Resolution	1 bpm	1 bpm
Precision	20~200 bpm: 5% or ±5bpm; 201~350 bpm: 10%.	1 bpm or ±1%
Alarm setting	The limit of alarm (setup range : 20~350 bpm), and leads-off alarm display.	15~350 bpm
Input resistance	≥5 MΩ	≥5 MΩ
CMRR	≥89 dB	Diagnostic mode: ≥90dB Monitoring mode: ≥105dB Surgical mode: ≥105dB
Heart disorder analysis	NO	NO
Anti-polarized voltage	≤±500 mV	3/5 lead ≤±300mV; 12 lead ≤±500mV.
Baseline renewing time	<5 s after the defibrillation	<5 s after the defibrillation
ECG mode	Mode 1 (Monitoring mode), mode 2(Monitoring mode), mode 3 (Surgical mode)	Diagnostic mode, Monitoring mode, Surgical mode.
Frequency characteristic	Mode 1 : 0.1Hz-40Hz; Mode 2 : 0.67Hz-40Hz Mode 3 : 1Hz-25Hz	Diagnostic mode: 0.05Hz-100Hz Monitoring mode: 0.5Hz-40Hz Surgical mode: 1Hz-20Hz
Safeguard	4000V high voltage isolation, anti-defibrillation	Withstand 4000VAC/50Hz voltage in isolation; Against electrosurgical interference and defibrillation

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3. Respiration

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
Measuring method	The thorax impedance method (used with ECG lead)	Thoracic impedance
Measuring range	15 ~ 120rpm	Adult: 0~120 rpm; Neonate/ Pediatric: 0~150 rpm
Resolution	1 rpm	1rpm
Precision	The bigger one between ±2 rpm or ±2 %	0~6 rpm: Unspecified; 7~120rpm: ±2 rpm or ±2%
Alarm setup	Yes	Yes
Alarm method	Audible and visual alarm, alarm events recallable	Audible and visual alarm, alarm events recallable

4. Non-Invasive Blood Pressure (NIBP)

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
Method	Oscillometric	Oscillometric
Patient type	Neonatal, pediatric and adult patients	Neonatal, pediatric and adult patients
Unit of measure	mmHg & kPa	mmHg & kPa
Pressure measurement range – Systolic	Adult: 40 ~ 260mmHg pediatric: 40 ~ 160mmHg Neonate: 40 ~ 130mmHg	Adult: 40 ~ 270mmHg pediatric: 40~200mmHg Neonate: 40 ~ 135mmHg
Pressure measurement range – Diastolic	Adult: 20 ~ 200mmHg pediatric: 20 ~ 120mmHg Neonate: 20 ~ 100mmHg	Adult: 10 ~ 210mmHg pediatric: 10 ~ 150mmHg Neonate: 10 ~ 100mmHg
Pressure measurement	Adult: 26 ~ 220mmHg	Adult: 20 ~ 230mmHg

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range-Dean pressure	pediatric: 26 ~ 133mmHg Neonate: 26 ~ 110mmHg	pediatric: 20 ~ 165mmHg Neonate: 20 ~ 110mmHg
BP accuracy	Arithmetic mean values:±5 mmHg; Standard deviation no greater than 8 mmHg.	Arithmetic mean values:±5 mmHg; Standard deviation no greater than 8 mmHg.
BP measurement accuracy	ANSI/AAMI SP10:2002; EN1060-4	Meets ANSI/AAMI SP10:1992+A1:2002
Cuff pressure range	0 to 300mmHg	0 to 300mmHg
Auto zero CAL	Yes	Yes
Over pressure protector	Adult/ Pediatric: 300mmHg; Neonate: 150mmHg	Adult: 297±3mmHg Pediatric: 240±3mmHg Neonate: 147±3mmHg
Alarm setup	The range is the same as parameter measurement range of SYS、DIA、MAP	The range is the same as parameter measurement range of SYS、DIA、MAP
Alarm method	Sound light alarm, and record the alarm status for review	Sound light alarm, and record the alarm status for review

5. Pulse Oximetry (SpO2)

Characteristics	**Subject Device**	**Claimed SE Device 510(K) No.**
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
SpO2 module	Nellcor SpO2	Nellcor SpO2
Patient type	Adult, Pediatric & Neonate	Adult, Pediatric & Neonate
SpO2 measurement range	0 ~ 100%	0~ 100%
SpO2 measurement accuracy	adult/ Pediatric: 70~100%: ±2%; 0~69%: Unspecified. neonate 70~100%: ±3%; 0~69%: Unspecified.	adult/ Pediatric: 70~100%: ±2%; 0~69%: Unspecified. neonate 70~100%: ±3%; 0~69%: Unspecified.
Alarm range(%)	0~100%	0~100%
Pulse rate measurement	20~250bpm	20 to 250 BPM

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No.	Category	Directives/Standards	Title & Comments
1	General	93/42/EEC	Medical Device Directive
		21CFR820	Code of Federal Regulations
		91/157/EEC	Battery Declaration Directive
		93/86/EEC	Battery Disposal Directive
		IEC60601-1:1988 A1:1991,+ A2:1995	General requirements for Safety and Essential Performance
		IEC60601-1-1:2000	Medical electrical equipment -- Part 1: General requirements for safety- Collateral standard-Safety requirements for medical electrical systems
		IEC60601-1-4:2000	Programmable medical systems
		IEC 60601-1-6:2006	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
		IEC 60601-1-8：2006	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
		IEC 60601-2-25	Medical electrical equipment, Part 2-25: Particular requirements for the safety of electrocardiographs
		IEC 60601-2-27: 2005	Medical electrical equipment -- Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment. (Cardiovascular)
		IEC 60601-2-49:2001	Medical electrical equipment --- Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
		ISO14971:2007	Medical devices-Application of risk management to medical devices
2	Alarm	IEC60601-1-8 2006	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
3	NIBP	AAMI SP 10:2002	Electronic or Automated Sphygmomanometers
		EN1060-1:1995	Non-invasive sphygmomanometers - Part 1: General requirements
		EN1060-3:1997	Non-invasive sphygmomanometers – Part 3: supplementary requirements for electro-mechanical blood pressure measuring systems

		EN1060-4: 2004	Non-invasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.
		IEC60601-2-30:1999	Medical Electrical Equipment-Part 2-30: Particular requirements for safety of automatic cycling indirect blood pressure monitoring equipment.
5	SpO2	EN 865:1997	Pulse oximeters, Particular requirements
		ISO 9919:2005	Medical electrical equipment --- Part 2-34: Particular requirements for the basic safety and essential performance of pulse oximeters equipment for medical use
6	Temperature	ASTM E1112:2000	Electronic thermometer for intermittent determination of patient temperature
		ASTM E1104-03	Standard Specification for Clinical Thermometer Probe Covers and Sheaths
		EN 12470-4:2000	Clinical thermometers-Part 4: Performance of electrical thermometers for continuous measurement.
7	ECG Measurement	ANSI/AAMI EC11:1991/(R)2001	Diagnostic electrocardiographic devices
		AAMI/ANSI EC13:2002/(R)2007	Cardiac monitors, heart rate meters, and alarms
		ANSI/AAMI EC I2:2000/(R) 2005	Disposable ECG electrodes
		AAMI EC53/(R) 2001	ECG cables and leadwires. (Cardiovascular)
8	EMC	IEC60601-1-2:2007	Medical Electrical Equipment-Part 1-2:General Requirements for Safety - 2.Collateral Standard-Electromagnetic compatibility - Requirements and tests
		IEC61000-3-2	Harmonic Emission
		IEC61000-3-3	Voltage Fluctuations/Flicker Emission
		IEC61000-4-2	Electrostatic Discharge (ESD)
		IEC61000-4-3	Radiated RF electromagnetic field
		IEC61000-4-4	Electrical fast Transient/Burst (EFT)
		IEC61000-4-5	Surge current
		IEC61000-4-6	Conducted disturbances, induced by RF field
		IEC61000-4-8	Power frequency (50/60Hz) Magnetic field
		IEC61000-4-11	Voltage dips, short interruptions, and voltage variation on power supply input lines
		CISPR 11, EN55011	RF emissions

9	Biocompatibility	ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
		ISO10993-5	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
		ISO10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
10	Labeling	EN1041:1998	Terminology, symbols and information provided with medical devices - information supplied by the manufacturer with medical devices.
11	Marking	IEC60878, EN980, ISO7000, EN60417-1, EN60417-2	Graphical Symbols for use in the labeling of Medical Devices
12	Package	ISTA: Pre-Shipment Test Procedures (Procedure 1A, 1994 Rev.)	Pre-Shipment Test Procedures (Package)
13	Reliability	IEC60068-2-1	Environmental testing - Part 2-1: Tests - Test A: Cold
		IEC60068-2-2	Environmental testing - Part 2-2: Tests - Test B: Dry heat
		IEC 60068-2-6	Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
		IEC 60068-2-27	Environmental testing - Part 2-27: Tests - Te st Ea and guidance: Shock
		IEC60068-2-30	Environmental testing- Part 2-30: Tests - Tes t Db: Damp heat, cyclic
		IEC 60068-2-64	Environmental testing - Part 2-64: Tests - Te st Fh: Vibration, broadband random and guid ance

range		
Pulse rate accuracy	±3bpm (Geostationary) Or ±5 bpm (Campaign)	±3bpm (Geostationary) Or ±5 bpm (Campaign)
Alarm range–Pulse rate (bpm)	20~250bpm	20~250bpm

Note: Because the same NELLCOR SPO2 module and the sensors and cables are used in PM-9000 EXPRESS PATIENT MONITOR (K053234), the Characteristics are same.

6. Temperature (Predictive & Monitor)

Characteristics	**Subject Device**	**Claimed SE Device 510(K) No.**
Name and model	PMS8210A Multi-parameter Patient Monitor	PM-9000 EXPRESS PATIENT MONITOR (K053234)
Temperature parameter	Optional parameter	Optional parameter
Patient type	Adult, Pediatric & Neonate	Adult, Pediatric & Neonate
Unit of measure	°C & °F	°C & °F
Measurement site	Oral, Rectal & Axillary	Oral, Rectal & Axillary
Temperature measurement range	0°C~50°C (32~122°F)	0°C~50°C (32~122°F)
Temperature measurement accuracy	±0.1°C (±0.2°F) ASTM E1112:00	±0.1°C (±0.2°F) ASTM E1112:00
Probe cross contamination control	Single use Disposable cover	Single use Disposable cover

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7. Safety and Performance Data :

Please refer to the Declaration of Conformity for the comprehensive list of testing performed on the PMS8210A Multi-parameter Patient Monitor. The PMS8210A has undergone Third Party safety testing in accordance with IEC standards and completed performance testing in accordance with IEC standards. In that this device has software of Moderate concern; the appropriate level of Software evaluation was performed.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Shanghai 3F Electronics Co., Ltd. concludes that the Patient Monitor, Model PMS8210A, is safe and effective and substantially equivalent to predicate devices as described herein.

9. Shanghai 3F Electronics Co., Ltd.will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Shanghai 3F Electronics Co., Ltd.
c/o Mr. Charles Mack
Principal Engineer
International Regulatory Consultants (IRC)
77325 Joyce Way
Echo, OR 97826

Re: K100394
Trade/Device Name: PMS8210A (IRIS) Multi-parameter Patient Monitor
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: February 7, 2010
Received: February 16, 2010

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PMS8210A (IRIS) Multi-parameter Patient Monitor

Indications for Use:

The PMS8210A Multi Parameter Patient Monitor is a multi-parameters monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PMS8210A Patient Monitor has certain features and functions.

The patient parameters that can be monitored by PMS8210A Patient Monitor are: ECG(3-lead or 5-lead selectable), Heart Rate(HR), Pulse Rate(PR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Arterial Hemoglobin Oxygen Saturation(SpO2) and Temperature (TEMP). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PMS8210A Patient Monitor is intended for use in a health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PMS8210A Patient Monitor is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician.

Prescription Use ___ √ __ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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